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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/512,914 | 02/25/00 | BUCH J | PC 9919ARTR |

HM12/0104

Pfizer Inc
Patent Department
Box 519
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| EXAMINER | |
|---|---|
| JIANG,S | |
| **ART UNIT** | **PAPER NUMBER** |
| 1617 | 4 |

**DATE MAILED:** 01/04/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. 09/512,914 | Applicant(s) BUCH ET AL. | |
|---|---|---|---|
| | Examiner Shaojia A. Jiang | Art Unit 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-117* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-117* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

## DETAILED ACTION

This application claims priority to provisional application Serial No. 60/057275.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3 drawn to a single pharmaceutical composition classified in class 514, subclass 356, 422 and 423.

II. Claims 4-15 drawn to the use of two pharmaceutical compositions together or a first pharmaceutical composition for use with a second pharmaceutical composition for achieving an antihypertensive effect and a hypolipidemic effect in a mammal, classified in class 514, subclass 356, 422 and 423.

III. Claims 16-27 drawn to the use of two pharmaceutical compositions together or a first pharmaceutical composition for use with a second pharmaceutical composition for achieving an antianginal effect in a mammal, classified in class 514, subclass 356, 422 and 423.

IV. Claims 28-71 drawn to the use of two pharmaceutical compositions together or a first pharmaceutical composition for use with a second pharmaceutical composition for achieving an antiatherosclerotic effect in a mammal, classified in class 514, subclass 356, 422 and 423.

V. Claims 72-83 drawn to the use of two pharmaceutical compositions together or a first pharmaceutical composition for use with a second

pharmaceutical composition for managing cardiac risk in a mammal, classified in class 514, subclass 356, 422 and 423.

VI. Claims 84-98 drawn to a kit for achieving a therapeutic effect in a mammal, classified in class 514, subclass 356, 422 and 423.

VII. Claims 99-117 drawn to a method for therapeutic treatments in a mammal employing a first and second compound, classified in class 514, subclass 356, 422 and 423.

Inventions I-VI are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are separate and distinct each from the other because they have different functions as well as single vs. multiple compositions and various uses for compositions.

The invention of Group I is a single pharmaceutical composition to be administered to the host without a specific function. The invention of Group II functions to treat hypertensive and hypolipidemic disorders in a mammal. The invention of Group III functions to treat anginal disorder in a mammal. The invention of Group IV functions to treat atherosclerotic disorder in a mammal. The invention of Group V functions to manage cardiac risk in a mammal. The invention of Group VI is drawn to a kit used for achieving a therapeutic effect in a mammal. Therefore Group I-VI have different functions.

Inventions I-VI; and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product such as β–blockers, calcium channel blockers, and angiotension converting enzyme inhibitors.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

***Election of Species***

This application contains claims directed to the following patentably distinct species of the claimed inventions: Groups I, VI and VII.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. In the instant case applicant is required to elect a specific disease or condition to be treated for prosecution, e.g., antihypertension or

antiatherosclerosis. Claims 1-3 of Group I, claims 84-86 of Group VI and claims 99-105 of Group VII would be considered generic to a plurality of disclosed patentably distinct species.

Since each method of use and treatment relates to a separate and distinct area of pharmaceutical technology, the search for all inventions would place an undue burden on the office in view of the diversity of the medical disorders to be treated and the corresponding diversity in the field of search for each. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Because the above restriction/election requirement is complex, a telephone call to applicant's agent to request an oral election was not made. See M.P.E.P Sec. 812.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shaojia Anna Jiang, Ph.D. whose telephone number is (703)305-1008. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)305-1235.

Shaojia Anna Jiang

Patent Examiner
January 2, 2001

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600